

Question Paper

Exam Date & Time: 07-May-2018 (02:00 PM - 05:00 PM)



MANIPAL ACADEMY OF HIGHER EDUCATION

MANIPAL COLLEGE OF PHARMACEUTICAL SCIENCES
END SEMESTER THEORY EXAMINATIONS- MAY 2018
PROGRAM: MPHARM SEMESTER 2 (PHARMACEUTICAL ANALYSIS)

DATE: 07/05/2018

TIME: 2:00 PM - 5:00 PM

Quality Control and Quality Assurance [PCH-MPA203T]

Marks: 50

Duration: 180 mins.

a

Answer all the questions.

Answer the following (5 marks x 8 = 40 marks)

- 1) What is Master Formula Record? Write the procedure to make a MFR (5)
- 2) How packaging operations are carried out? Explain in detail. (5)
- 3) Explain the WHO guidelines for distribution records. (5)
- 4) Explain the hydrolytic resistance test for glass containers. (5)
- 5) Discuss the cGMP guidelines as per FDA (5)
- 6) Discuss any two methods for the analysis of raw materials. (5)
- 7) Explain the test procedures and acceptance criteria for new drug substance (5)
- 8) Give the detailed set of guidelines for handling of animals as per CPCSEA (5)

b

Answer all the questions.

Answer the following with specific answers (2 marks x 5 = 10 marks)

- 9) Enlist the Quality control tests for suppositories. (2)
 - A)
 - B) How will you calculate percentage yield? Explain (2)
 - C) List down the contents of standard operating procedure. (2)
 - D) (2)

How do you carry out the test procedures for the finished products?

E)

What are the objectives of GLP?

(2)

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